

Disclaimer will be filed to address this rejection. Therefore, Applicants believe that they have been fully responsive to this provisional rejection.

In the Office Action, claims 1-12, 14-20 and 22 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,504,072 ("*Schmidt*"). Applicants respectfully submit that this rejection is improper.

Of the presently pending claims, claims 1, 7, 14, and 19 are the sole independent claims. Independent claim 1 recites an enteral composition that includes a protein source consisting of hydrolyzed whey protein; a carbohydrate source; and a lipid source wherein the enteral composition has a caloric density of at least 1.4 kcal/mL and wherein the composition provides a ratio of non-protein calories per gram of nitrogen of at least 90:1. Independent claim 7 recites a method for providing nutrition to a metabolically stressed patient that includes administering to the patient a therapeutically effective amount of a composition that includes, in part, a protein source having approximately 15% to about 20% of the calorie distribution of the composition wherein the protein source consists essentially of hydrolyzed whey protein. The composition further includes, in part, a caloric density of at least 1.4 kcal/mL and provide a ratio of non-protein calories per gram of nitrogen of at least approximately 90:1.

Independent claim 14 recites an enteral composition for a metabolically stressed patient wherein about 15% to about 20% of the calorie distribution of the composition consists essentially of hydrolyzed whey protein. The enteral composition further includes, in part, a caloric density of at least 1.4 kcal/mL and a ratio of non-protein calories per gram of nitrogen of at least 90:1. Independent claim 19 recites a method for providing nutrition to a metabolically stressed patient that includes administering to the patient a therapeutically effective amount of a composition. The composition includes, in part, a protein source having approximately 15% to about 20% of the calorie distribution of the composition wherein the protein source consists essentially of hydrolyzed whey protein. The composition further includes, in part, a caloric density of at least 1.4 kcal/mL and provides a ratio of non-protein calories per gram of nitrogen of at least approximately 90:1.

The claimed invention provides a product that is specifically directed to meet nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. To this

end, the claimed invention provides calorically dense nutritional support in the form of an enteral composition while at the same time providing a moderate non-protein calories per gram of nitrogen ("NPC/gN") ratio. The nutritional diet of the claimed invention preferably utilizes, for example, hydrolyzed whey protein to enhance absorption in the metabolically stressed patients. See, Specification, Page 6, line 23 to Page 7, line 4.

As previously discussed, the enteral composition of the claimed invention includes, in part, a caloric density of at least 1.4 kcal/mL wherein the composition provides a ratio of non-protein calories per gram of nitrogen of at least 90:1. The composition can further include, in part, a protein source that provides about 15% to about 20% of the calorie distribution of the composition. For adults and older children (10 plus years or older), for example, the protein concentration of the claimed invention is optimal for moderate tissue repair needs of the targeted patient populations without imposing an undue nitrogen burden on renal function. See, Specification, Page 4, lines 4-17.

In contrast, *Schmidl* fails to disclose or suggest a number of features of the claimed invention. Of course, an anticipation rejection requires that "there must be no difference between the claimed invention and a reference's disclosure as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Accordingly, "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990).

Indeed, *Schmidl* fails to disclose or suggest, for example, an enteral composition that has a caloric density of 1.4 kcal/mL as required by the claimed invention. This is a critical issue with respect to the patient population of Applicants' claimed invention. In contrast to the claimed invention, *Schmidl* states "the composition can also be in the form of a ready-to-use aqueous liquid which preferably has a caloric content of 1 kcal/mL." See, *Schmidl* column 7, lines 54-57.

If anything, *Schmidl* teaches away from the claimed invention. The mere fact that a composition has lipids, carbohydrates, and protein does not mean the composition has the same caloric density as another composition including lipids, carbohydrates, and proteins. Simply because a product has lipids, carbohydrates, and protein does not mean it has the same

characteristics as another product having lipids, carbohydrates, and protein. There are millions of compositions including a lipid, a carbohydrate, and a protein that have different properties. Thus, clearly the anticipation rejection is improper in view of this fact alone.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, claims 1-12, 14-20 and 22 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,221,668 ("*Henningfield*"). Applicants believe that *Henningfield*, like *Schmidl*, fails to disclose or suggest a number of features of the claimed invention.

For example, Applicants do not believe that *Henningfield* discloses or suggests an enteral composition that includes, for example, a protein source consisting of hydrolyzed whey protein wherein the enteral composition has a caloric density of at least 1.4 kcal/mL and provides a ratio of non-protein calories per gram of nitrogen of at least 90:1. In this regard, the preferred caloric density of the nutritional product in *Henningfield* is 1.3 kcal/mL. See, *Henningfield*, column 9, lines 10-12. Moreover, Applicants do not believe that *Henningfield* discloses or suggests that the protein source is limited to hydrolyzed whey protein as required by claim 1.

Further, Applicants do not believe that *Henningfield* discloses or suggests an enteral composition that includes, in part, a hydrolyzed whey protein source having about 15% to about 20% of the calorie distribution of the composition as required by independent claims 7, 14 and 19. As previously discussed, Applicants have found that the total amount of energy provided by the protein source of the claimed invention is optimal for moderate tissue repair needs of the targeted patient populations without imposing an undue nitrogen burden on renal function. Indeed, *Henningfield* discloses that about 20.5% of the calories provided by protein is most preferred. See, *Henningfield*, column 9, lines 28-29. Moreover, the *Henningfield* composition is intended for trauma patients, especially severe injury. See, *Henningfield*, column 1, lines 10-15. In contrast, the enteral compositions of the claimed invention are for metabolically stressed patients, particularly patients that have compromised absorptive capacity. One skilled in the art viewing *Henningfield* would clearly consider *Henningfield*, for at least the reasons discussed above, to be deficient with respect to the specific compositional features of the claimed

invention. Therefore, Applicants believe that *Henningfield* fails to anticipate the claimed invention.

Accordingly, Applicants request that this rejection be withdrawn.

In the Office Action, claims 1-22 are rejected under 35 U.S.C. § 102 as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5, 714,472 ("*Gray*"). Applicants believe that *Gray*, like *Henningfield* and/or *Schmidl*, fail to disclose or suggest a number of features of the claimed invention.

For example, Applicants do not believe that *Gray*, like *Henningfield*, discloses or suggests an enteral composition for metabolically stressed patients that includes, in part, a hydrolyzed whey protein source with about 15% to about 20% of the energy content of the composition. Indeed, the Examiner admits that *Gray* merely provides "about 22%" of the energy of the composition. See, Office Action, page 7. This is clearly not substantially the same as an enteral composition with a protein energy content of about 15% to about 20% as the Examiner would seem to suggest.

*Gray* also discloses that the total non-protein calories per gram of nitrogen should be less than or equal to 70:1. This clearly contrasts the claimed invention which requires, in part, a ratio of non-protein calories per gram of nitrogen of at least about 90:1. Moreover, *Gray* clearly fails to disclose or suggest an enteral composition that includes, in part, about 0.1% to 2.0% of free amino acids as required by Claim 17. In this regard, Applicants believe that one skilled in the art viewing *Gray* (see, for example, column 4, lines 49-67) would consider the free amino acid content disclosed in *Gray* to be appreciably higher than the free amino acid content of the claimed invention. Therefore, Applicants do not believe that *Gray* anticipates and/or renders obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 13 and 21 are rejected under 35 U.S.C. § 103 as being unpatentable over *Schmidl* in view of *Gray*. Claims 13 and 21 depend from independent claims 7 and 19, respectively, and therefore as a matter of law incorporate each of the features of their respective independent claims.

In contrast, *Schmidl* and/or *Gray*, even if combinable, fail to disclose or suggest a number of features of claims 13 and 21. In this regard, the Examiner admits that *Schmidl* fails to incorporate beta-carotene and L-cystine into their enteral formula. See, Office Action, page 9. The Examiner relies on the purported teachings of *Gray* to remedy this deficiency.

However, *Schmidl* is also clearly deficient with respect to an enteral composition that has a caloric density of at least about 1.4 kcal/ml as required by the claimed invention. In fact, the preferred caloric density of *Schmidl* is 1.0 kcal/ml. This effectively teaches away from claimed invention as previously discussed. Again, the Examiner appears to merely rely on *Gray* for its purported teachings regarding the beta-carotene feature of Claims 13 and 21. Therefore, Applicants do not believe that *Schmidl* and *Gray*, even if combinable, render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,166,189 ("*Trimbo*") in view of *Schmidl*, *Gray*, U.S. Patent No. 4,427,658 ("*Maubois*") and further in view of *Granger et al.* The Patent Office primarily relies on *Trimbo* and thus relies on the other cited references to remedy its deficiencies.

In contrast, the cited art fails to disclose or suggest a number of features of the claimed invention. For example, *Trimbo* is deficient with respect to a number of features of the claimed invention as even admitted by the Examiner. See, Office Action, page 10. For example, *Trimbo* is deficient with respect to an enteral composition suitable for metabolically stressed patients that includes, in part, a hydrolyzed whey protein source providing about 15% to about 20% of the energy content wherein the composition has a caloric density of at least about 1.4 kcal/ml.

Indeed, *Trimbo* discloses, for example, that the composition has an energy content of 1.2 kcal/ml. As previously discussed, the enteral composition includes a hydrolyzed whey protein source that can provide about 15% to about 20% of the total energy of the composition wherein the enteral composition has a caloric density of at least about 1.4 kcal/ml. As previously discussed, the claimed invention provides a calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate NPC/gN ratio specifically directed

to meet the nutritional needs of metabolically stressed patients without elevated levels or excess fluid. See, Specification, Page 6, lines 23-28.

Further, the remaining references, even if combinable, cannot remedy the deficiencies of *Trimbo*. For example, nowhere do any of these references, alone or in combination, disclose or suggest the specific compositional features for the claimed invention including, for example, the protein energy content and caloric density features of the claimed invention. As previously discussed, *Schmidl* effectively teaches away from the caloric density of the claimed invention. Further, *Gray* discloses a protein source energy content that is clearly outside of the scope and content of the claimed invention as discussed above.

Contrary to the Patent Office's position, *Maubois* fails to disclose or suggest, for example, protein intake ranging from 7% to 25% of the total caloric intake. Examples 5 and 6 merely suggest that the protein intake can be 7% to 12% (Example 5) or 25% of the total caloric intake. This clearly does not suggest the protein energy content of 15% to 20% as required by the claimed invention. Moreover, the Patent Office merely relies on *Granger* for its purported teaching relating to providing elemental protein to hypermetabolically stressed patients. Therefore, Applicants do not believe that one skilled in the art viewing the cited art, in any hypothetical combination, would be inclined to modify *Trimbo* to arrive at the claimed invention.

What the Patent Office clearly has done is to simply piece together the cited art by selectively picking and choosing teachings from disparate art in an attempt to explain what the claimed invention discloses. The Court of Appeals for the Federal Circuit has criticized this motivation to combine analysis as being "hindsight reconstructive" because the motivation to combine the references was first disclosed in the present invention. *In re O'Farrell*, 853 F.2d 894, 902-903 (Fed. Cir. 1988).

As previously discussed, *Trimbo* is clearly deficient with respect to a number of features of the claimed invention as even admitted by the Patent Office. Further, nowhere does any one or any hypothetical combination of the remaining references disclose or suggest the specific compositional features of the claimed invention, for example, an enteral composition that includes a hydrolyzed whey protein source that provides about 15% to about 20% of the energy of the composition and/or that has a caloric density of at least 1.4 kcal/ml. For example, *Schmidl*

and *Gray* effectively teach away from the specific compositional features of the claimed invention as previously discussed. Further, *Maubois* is clearly deficient, for example, with respect to the protein energy content of the claimed invention. Indeed, *Maubois* fails to specifically address the U.S. RDA's nutritional needs of metabolically stressed patients as even admitted by the Examiner. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the present application and earnestly solicit allowance of same.

Respectfully submitted,

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